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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540

7590 05/05/2004

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/657,446

Applicant(s)

EDGREN ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46, 48 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46, 48 and 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/25/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time filed 01/20/04, amendment and remarks filed 02/17/04 and IDS filed 02/25/04.

#### ***Claim Rejections - 35 USC § 102***

1. Applicants argument regarding claims 46, 48, 51-58 and 60 rejected under 35 U.S.C. 102(b) as being anticipated by Kjornaes et al. (US 4,713,248) is persuasive because Kjornaes does not disclose a passageway or pore or hole in the membrane and the rejection is withdrawn.
2. Claims 46, 48, 51-58 and 60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,558,879).

Applicants argue that the outer membrane of Chen dissolves always during operation while the outer (second) and inner (first) membranes of the instant claims partially dissolve and always exist.

Applicants further argue that the membrane coating of Chen has poor tensile property such that when the coating is under tension, the coating ruptures in-situ. Applicants argue that the first and second membranes of the instant formulation are made of mostly water-insoluble polymer and leachable water-soluble polymers respectively, whereas the second outer coating of Chen is made of water-soluble polymer such as hydroxypropylcellulose. Applicants also argue that the membrane of Chen is weakened by the presence of pore forming material. Further more, applicants cite Rowe as applicants explain the relationship of tensile strength to rupturability and specifically that the ethylcellulose of Chen is brittle and ruptures under tension

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teaching away from second membrane of the instant claims. Applicants also state that the instant high tensile cellulose acetate is an example of a suitable material for the second membrane. Applicants then state that in view of the arguments, Chen does not anticipate the claims.

### *Response to Arguments*

3. Applicants' arguments filed 02/17/04 have been fully considered but they are not persuasive.

Applicants admit that the second membrane is leachable and soluble (lines 5 and 6 of page 10 of the amendment filed 02/17/04). Regarding the argument that the second (outer) membrane of Chen dissolves does not teach away from the instant application where the second membrane is composed of leachable and water soluble polymers. The second polymer of the instant claim is water-soluble and therefore, the outer membrane made of water-soluble polymer anticipates the second membrane. It is further respectfully noted that the limitation of water-soluble is not recited by the instant claims. Furthermore, no specific polymers are claimed.

Regarding the argument that the membrane of Chen dissolves always whereas the membrane of the instant claims partially dissolves and always exists, applicants presented no criteria why the water-soluble polymer of the Chen prior art dissolves and the water soluble and leachable polymer of the instant claims partially dissolves. The phrase partially dissolves is relative. At what point is the dissolution partial and at what point is the dissolution complete?

Regarding the issue that the ethylcellulose of the prior art is brittle because of poor tensile strength while cellulose acetate of the instant application has high tensile strength and the

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chemical and physical integrity of the second membrane is maintained, it is noted that a) applicants are relying on limitations that are not recited in the instant claims, b) high tensile strength and low tensile strength are relative terms, c) there is no recitation of any specific tensile strength value that would exclude Chen.

Regarding the presence of pore forming material in the membrane of Chen, it is noted that the instant claims do not exclude pore-forming materials from the membrane of the instant claims. Specifically, the instant claim broadly reads on a dosage form comprising a therapeutic agent, first membrane in contact with the formulation, a second membrane positioned over the first membrane and at least a passage way. The Chen prior art comprises a core of medicament, first inner coating layer and a second outer coating layer and a passageway that is formed in-situ as admitted by applicants. A passageway that is formed in-situ is a passageway. Chen meets the limitations of the claims.

4. Claims 46, 48 and 51-60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248).

Applicants argue that:

a) Bartoo does not “anticipate a first membrane layer with a permeability that responds to osmotic pressure as recited in the claims” because Bartoo discloses a subcoat whose permeability is sensitive to changes in pH and changes in environmental conditions.

Applicants state that in Bartoo, response of the dosage form to pH changes is a result of biological fluid entering the system through the passageway.

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b) Bartoo requires the use of acidic core formulation, which is contrary to the mechanism of osmoresponsive membranes since osmotic activity is directly proportional to the drug concentration.

c) The Bartoo reference “leads away from the use of precipitous internal change in osmotic system and does not anticipate it for use as a means to regulate permeability” because in applicants’ metformin HCl example, at the moment after the last solid crystal dissolves, the concentration of drug within the delivery system proceeds to decline parabolically with time.

***Response to Arguments***

5. Applicants' arguments filed 02/17/04 have been fully considered but they are not persuasive.

In response to a) above, it is respectfully noted that instant claim 46, does not define/recite the materials that compose/make up the membranes and a dosage form that meets the limitations a dosage form comprising a therapeutic agent, first and second membranes and a passageway would respond to osmotic pressure as recited in the instant. There is no requirement in instant claim 46 that would indicate that such a formulation would not respond to osmotic pressure.

In response to b), it is respectfully noted that there is no drug concentration parameter in the claims. And in this case applicants are relying on limitations that are not recited in the rejected claims and the rejected claims do not exclude acidic core.

In response to c), it is respectfully noted that the claims do not recite metformin HCl and comparing applicants unclaimed example relies on limitations that are not recited in the claims.

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The recitation of “that maintains its physical and chemical integrity as the dosage form dispenses the therapeutic agent” is not given patentable weight to a formulation comprising, therapeutic agent, first and second membranes and a passageway.

No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
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